Dated: May 25, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–12362 Filed 5–26–04; 3:59 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0042]

Draft Guidances for Industry on Improving Information About Medical Products and Health Conditions; Availability; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until August 10, 2004, the comment period for the draft guidances entitled ''Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements,'' ''Help-Seeking and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms,'' and ''Consumer-Directed Broadcast Advertising of Restricted Devices.'' FDA published a notice of availability of the draft guidances in the **Federal Register** of February 10, 2004 (69 FR 6308). FDA is taking this action in response to requests for an extension and to allow interested parties additional time to submit comments.

DATES: Submit written or electronic comments on the draft guidances by August 10, 2004. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidances to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidances to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance documents.

FOR FURTHER INFORMATION CONTACT:

Regarding prescription human drugs: Lesley R. Frank, Center for Drug Evaluation and Research (HFD–42), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2831.

Regarding prescription human biological products: Glenn N. Byrd, Center for Biologics Evaluation and Research (HFM–600), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3028.

Regarding medical device products: Deborah Wolf, Center for Devices and Radiological Health (HFZ–300), 2098 Gaither Rd., Rockville, MD 20850, 301–594–4589.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 10, 2004 (69 FR 6308), FDA published a document announcing the availability of three draft guidance documents entitled ''Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements,'' ''Help-Seeking and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms,'' and ''Consumer-Directed Broadcast Advertising of Restricted Devices.'' The draft guidances are intended to provide clear advice to medical product firms on how to fulfill the requirements in FDA's rules applicable to certain communications to consumers and health care professionals.

In the February 2004 notice of availability, FDA specifically requested comments on a number of issues addressed in the draft guidances. The agency also requested submission of research and data related to these issues. The initial comment period closed on May 10, 2004. FDA received a request dated April 2, 2004, and numerous requests dated May 8, 2004, that the agency extend the comment period. The requests cite the need for additional time because of the importance of the subject matter to be commented on. The requests also state an extension is needed for consultation with interested parties, to complete research, and to prepare comments. In response to these requests, FDA has decided to reopen the comment period until August 10, 2004.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written comments on the draft guidance documents by August 10, 2004. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. Comments should identify clearly which guidance they are commenting on. The draft guidance documents and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Copies of the draft guidances are available on the Internet at *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines*, or *http://ww.fda.gov/ohrms/dockets/default.htm*.

Dated: May 25, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–12270 Filed 5–28–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Proposed Project: 2004–2006 National Survey on Drug Use and Health: Methodological Field Tests—New—The National Survey on Drug Use and Health (NSDUH), formerly the National Household Survey on Drug Abuse (NHSDA), is a survey of the civilian, noninstitutionalized population of the United States 12 years of age and older. The data are used to determine the prevalence of use of tobacco products, alcohol, illicit substances, and illicit use of prescription drugs. The results are used by SAMHSA, ONDCP, Federal government agencies, and other organizations and researchers to establish policy, direct program activities, and better allocate resources.

This will be a request for generic approval for information collection for NSDUH methodological field tests designed to examine the feasibility,

quality, and efficiency of new procedures or revisions to the existing survey protocol. These field tests will examine ways to increase data quality, lower operating costs, and gain a better understanding of various sources of nonsampling error. If these tests provide successful results, current procedures may be revised and incorporated into the main study (*e.g.*, questionnaire changes). Particular attention will be given to minimizing the impact of design changes so that survey data continue to remain comparable over time.

Field test activities are expected to include validating new questions on depression; examining data reliability through the use of test-retest procedures; improving response rates among persons residing in controlled access communities (locked apartment buildings, gated communities, college dormitories, etc.), persons aged 50 or over, and other hard-to-reach populations; and conducting a nonresponse follow-up study. Cognitive laboratory testing will be conducted prior to the implementation of significant questionnaire modifications. These questionnaire modifications will also be pre-tested and the feasibility of text-to-speech software determined. To understand the effectiveness of the current monetary incentive, a new incentive study will be conducted with varying incentive amounts. The relationship between incentives and veracity of reporting will also be examined. Lastly, there will be a test to determine the feasibility of selecting a maximum of three persons per dwelling unit instead of two (triad sampling). Some of the above studies may be combined to introduce survey efficiencies.

The average annual burden associated with these activities over a three-year period is summarized below:

Activity	Number of respondents	Responses per respondent	Average burden per response (hrs.)	Total burden (hrs.)
a. Reliability/depression module validity study	2,001	2	1.5	6,003
b. Focus groups with 50+ populations	132	1	2.0	264
c. Improving participation among controlled access and 50+ population, and other hard-to-reach populations	1,251	1	1.0	1,251
d. Nonresponse follow-up	1,251	1	1.0	1,251
e. Incentive/validity study	1,251	1	1.0	1,251
f. Cognitive laboratory testing	501	1	1.0	501
g. Annual questionnaire pre-test	999	1	1.0	999
h. Text-to-speech software for voices in computer-assisted interviewing	249	1	1.0	249
i. Triad sampling	999	1	1.0	999
Household screening for a–d, f, h, and i	21,313	1	0.083	1,769
Screening Verification for a, c, d, e, g, and i	638	1	0.067	43
Interview Verification for a, c, d, e, g, and i	1,163	1	0.067	78
Total	22,063	.....	.....	14,658

Estimate Burden for Groups with 50+ Population (also included in above burden table):

Activity	Number of respondents	Responses per respondent	Average burden per response (hrs.)	Total burden (hrs.)
Focus groups with 50+ populations	132	1	2.0	264
Household screening for a, b, c, d, e, g, and i	383	1	0.083	32
Total	383	.....	.....	296
Annual average (Total divided by 3 years)	128	.....	.....	99

Written comments and recommendations concerning the proposed information collection should be sent by July 1, 2004 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: (202) 395–6974.

Dated: May 20, 2004.

Anna Marsh,

Executive Officer, SAMHSA.

[FR Doc. 04–12236 Filed 5–28–04; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Prevention; Notice of Meeting

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the Substance Abuse and Mental Health Services Administration (SAMHSA) Drug Testing Advisory Board to be held in June 2004.